

Remarks

Claims 1-15 were previously pending in the subject application. By this amendment, the applicant has amended claims 1 and 13 and added new claim 16. No new subject matter has been added by this amendment. Support for the amendments and new claim can be found throughout the subject specification including, for example, at page 5, paragraph 30. Accordingly, claims 1-16 are now before the Examiner for consideration.

The amendments to the claims have been made in an effort to lend greater clarity to the claimed subject matter and to expedite prosecution. These amendments should not be interpreted to indicate that the applicant has agreed with, or acquiesced to, the rejections set forth in the outstanding Office Action. Favorable consideration of the claims now presented, in view of the remarks and amendments set forth herein, is earnestly solicited.

The subject invention provides a unique shield for protecting indwelling catheters and corresponding exit sites from debris and moisture. The protective shield of the subject invention is particularly advantageous because of its ease of use. The subject shield has two layers of protection; a first layer in the form of an inner bag and a second protective layer in the form of an outer cover that is sized such that the inner bag can be encompassed beneath the outer cover. In use, the inner bag receives the proximal end of the catheter and is affixed by adhesive material to the user's skin to form a protective seal. The outer cover is also affixed to the user's skin by adhesive material such that the inner bag is positioned within the peripheral edges of the outer cover and a protective seal is formed between the outer cover and the user's skin. Such an arrangement provides a unique and advantageous shield because the outer cover serves as a tarp to move water and debris away from the inner bag.

Claim 13 has been rejected under 35 U.S.C. §102(b) as being anticipated by Norby *et al.* (U.S. Patent Reissue No. 29,319). To the extent this ground for rejection might be applied to the amended claim 13, the applicant respectfully traverses the ground for this rejection because the Norby *et al.* reference does not teach the current applicant's advantageous catheter shield.

Although the Norby *et al.* system and the protective shield of the current invention share certain superficial similarities, a careful comparison of the two technologies reveals critical differences. Unlike the protective shield of the subject invention, a drainage system is disclosed by

Norby *et al.* in which an opening within a sheet of substantially gelatinous material is placed over a wound/incision to cover only the external area of the body surrounding the opening, see claims 1-5 and col. 2, lines 35-50, and does not cover the incision/wound itself. A plastic cap, bag, or cover (see claims 1-5) is then removably placed over the opening of the sheet to engage with the sheet and not the patient's skin. In contrast, the inner bag and the outer cover of the subject invention are both affixed to the patient's skin to provide a dual layered protective cover that seals out moisture and debris.

Certain characteristics of the inner bag and the outer cover further distinguish the currently claimed protective shield from the drainage system of Norby *et al.* The subject protective shield is composed of a flexible, fluid-impermeable inner bag and outer cover. As noted above, the outer cover is sized to accommodate the inner bag within its peripheral edges. In Norby *et al.*, there is no teaching or suggestion of a cap, bag, or cover that is sized to accommodate the sheet nor vice versa, a sheet that is sized to accommodate the cap, bag, or cover. Further, Norby *et al.* fails to disclose or suggest placing the cap, bag, or cover over the sheet such that the sheet is sealed within the peripheral edges of the cap, bag, or cover, or vice versa. Moreover, the sheet of Norby *et al.* is substantially composed of gelatinous material as opposed to the fluid, impermeable material of the present invention. Accordingly, there is no rationale for concluding that the currently claimed protective shield is the drainage system of Norby *et al.*

It is basic premise of patent law that, in order to anticipate, a single prior art reference must disclose within its four corners, each and every element of the claimed invention. In *Lindemann v. American Hoist and Derrick Co.*, 221 USPQ 481 (Fed. Cir. 1984), the court stated:

Anticipation requires the presence in a single prior art reference, disclosure of each and every element of the claimed invention, arranged as in the claim. *Connell v. Sears Roebuck and Co.*, 722 F.2d 1542, 220 USPQ 193 (Fed. Cir. 1983); *SSIH Equip. S.A. v. USITC*, 718 F.2d 365, 216 USPQ 678 (Fed. Cir. 1983). In deciding the issue of anticipation, the [examiner] must identify the elements of the claims, determine their meaning in light of the specification and prosecution history, and identify corresponding elements disclosed in the allegedly anticipating reference. *SSIH, supra*; *Kalman [v. Kimberly-Clarke]*, 713 F.2d 760, 218 USPQ 781 (Fed. Cir. 1983)] (emphasis added). 221 USPQ at 485.

In *Dewey & Almy Chem. Co. v. Mimex Co.*, Judge Learned Hand wrote:

No doctrine of the patent law is better established than that a prior patent . . . to be an anticipation must bear within its four corners adequate directions for the practice [of the subsequent invention] . . . if the earlier disclosure offers no more than a starting point . . . if it does not inform the art without more how to practice the new invention, it has not correspondingly enriched the store of common knowledge, and it is not an anticipation. 124 F.2d 986, 990; 52 USPQ 138 (2nd Cir. 1942).

Thus, the applicant respectfully submits that the drainage system described by Norby *et al.* in no way teaches or suggests the protective shield claimed by the current application, which provides (1) two layers of protection for an indwelling catheter and exit site using an inner bag and outer cover, (2) an inner bag and outer cover composed of flexible, fluid impermeable material, and (3) sealing the inner bag beneath the outer cover such that a protective seal is formed between the outer cover and the user's skin. Because Norby *et al.* does not disclose such a protective shield, the applicant's respectfully request reconsideration and withdrawal of the rejection of claim 13 under 35 U.S.C. §102(b).

Claim 14 has been objected to as being dependent on rejected base claim 13. As discussed above, the applicant respectfully submits that the anticipation rejection of claim 13 is improper because the Norby *et al.* does not disclose, within its four corners, a protective shield having the characteristics recited in the current claim 13. Accordingly, reconsideration and withdrawal of this objection is respectfully requested.

In view of the foregoing remarks and amendment, the applicants believe that the currently pending claims are in condition for allowance, and such action is respectfully requested.

The Commissioner is hereby authorized to charge any fees under 37 CFR §§1.16 or 1.17 as required by this paper to Deposit Account No. 19-0065.

The applicants also invite the Examiner to call the undersigned if clarification is needed on any of this response, or if the Examiner believes a telephone interview would expedite the prosecution of the subject application to completion.

Respectfully submitted,



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